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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,549	07/13/2000	TOSHIO MURAKAMI	193665USOPCT	1530

7590 03/13/2002

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/581,549

Applicant(s)

MURAKAMI ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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1. This action is in response to the amendment filed January 2, 2002. This action contains new grounds of rejection and is made non-final.

2. Newly submitted claims 7-11 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

I. Claims 1-7, drawn to a composition of matter, classified in Class 127, subclass 30 or Class 424, subclass 409.

II. Claims 7-10, drawn to a process of disintegrating a solid composition, classified in Class 424, subclass 439.

III. Claim 11, drawn to a process of making a solid compound, classified in Class 241, subclass 3.

Inventions II and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. Furthermore, the broadly claimed compositions may be used in materially different methods, such as in analytical processes or could be used as a medium in methods of growing cells. The compositions of invention I may be made by a method materially distinct from the method of invention III. While invention III recites a method of making a composition of claim 4 (invention I), the product made by invention III is materially distinct from the product of invention I because the products of invention I do not require excipient, a pharmaceutically active ingredient

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or a nutritional ingredient, do not include a sweetner, and do not require that the composition be in a granulated form.

Since applicant has received an action on the merits for the originally presented invention (invention I), this invention has been constructively elected by original presentation for prosecution on the merits. The product claim will thereby be examined alone. Accordingly, claims 7-11 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite over the recitation of "A solid composition composition of matter" because it is not clear as to whether the claim is intended to be limited to "a solid composition of matter" or to "a solid composition comprising a composition of matter".

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen (U.S. Patent No. 5,616,361).

Virtanen discloses compositions and solid compositions of matter comprising xylitol present in an amount of 94-98 wt %, with respect to the total weight of the solid composition (see columns 6-7). The solid compositions are in the form of granulates or tablets. It is a property of xylitol that it has a water solubility of 35 wt % or more at 37°C, is a solid at 30°C, and that a saturated aqueous solution of xylitol has a viscosity of 50 mPa·s at less than 37°C.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Roser (U.S. Patent No. 5,958,455).

Roser teaches solid compositions comprising trehalose in the form of dihydrate trehalose (TD), amorphous trehalose (AT), anhydrous amorphous trehalose (AAT), anhydrous crystalline trehalose (AAC) or mixtures thereof (columns 5 and 8). The reference teaches that the trehalose is present in an amount of about 40 to 99 wt % with respect to the total weight of the solid composition (see, e.g. Tables 1, 3 and 4). The solid compositions are in the form of tablets (column 5). It is a property of trehalose that it has a water solubility of 35 wt % or more at 37°C, is a solid at 30°C, and that a saturated aqueous solution of trehalose has a viscosity of 50 mPa·s at less than 37°C.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703) 605-1237.

Carla Myers

March 11, 2002

  
**CARLA J. MYERS**  
**PRIMARY EXAMINER**